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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/640,853

08/13/2003

Randall V. Sparer

P-10998.00

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08/01/2006

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/640,853		SPARER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	James W. Rogers, Ph.D.		1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/28/2006</u>   | 6) <input type="checkbox"/> Other: _____                                    |

***Response to Applicant Arguments/Remarks***

The Applicant Arguments/Remarks Made in an Amendment filed 06/28/2006 has been considered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (US 6,153,252), for the reasons set forth in the office action mailed 03/09/2006.

Applicant's arguments filed 06/28/2006 have been fully considered but they are not persuasive.

Applicant asserts that Hossainy does not provide a specific disclosure of a miscible polymer blend including an active agent.

The relevance of this assertion is unclear. Clearly, Hossainy teaches many hydrophobic and hydrophilic polymers that would be miscible when blended together and can contain an active ingredient, in order to form a miscible blend the polymer blend should contain at least one hydrophobic and one hydrophilic polymer which applicant does state in the further limitations in claims 7,16,26,27,38,40,60,61,67 and 68. Therefore since the polymers claimed in Hossainy are the same hydrophobic and hydrophilic polymers and can indeed be used in a blend, they are miscible.

Applicant asserts that there is no correlation between a miscible polymer blend with the delivery of an active agent in Hossainy.

The relevance of this assertion is unclear. Clearly, from the above Hossainy does teach miscible polymer blends and the specification in Hossainy clearly states that the top coat (either a film or matrix) can be used to deliver therapeutic and pharmaceutical agents.

Applicant asserts that only one copolymer was used in all the working examples and no polymer blend was exemplified.

Clearly the experimental section of a patent does not limit the scope of that patent and is used only to show how the invention can be used and many other combinations would be apparent to a person of ordinary skill in the art.

Applicant asserts that where the term blend is used a "miscible" blend is not the only interpretation.

The relevance of this assertion is unclear. Clearly from the above arguments Hossainy does disclose hydrophobic and hydrophilic polymers that would be miscible when blended together, whether or not other combinations of polymers would not be miscible is of no concern when applying this art to applicants claimed invention.

Applicant asserts that in Exhibit B defines a "miscible polymer blend" as "a polymer blend homogenous down to the molecular level".

The examiner interpreted miscible polymer blend to comprise at least two polymers, since there was no amendment to further limit this definition examiner relied on the claim interpretation that the two polymers are hydrophobic and hydrophilic when

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applying art, therefore the limitation of a miscible polymer blend is met. Even if the examiner used the definition above the Hossainy patent would still meet the limitation that the polymer blend is homogenous down to the molecular level because the polymers and blends of those polymers are the same as in applicants claimed invention, which examiner assumes would fit the above definition.

Applicant asserts that Hossainy is not enabled because the disclosure lacks enablement for an active agent delivery system that includes an active agent and a miscible polymer blend.

The relevance of this assertion is unclear. Clearly the specification discloses that a polymer blend of a hydrophobic and hydrophilic polymer can be used to coat a medical device while also delivering an active agent. Many of the polymers in Hossainy when blended together would be miscible, see above.

Applicant asserts that the examiners use of inherency because there is not specific disclosure that includes a combination of polymers that inherently form a miscible blend and can control the release of an active agent in an adjustable manner.

The relevance of this assertion is unclear. The examiner already stated above that since Hossainy teaches many hydrophobic and hydrophilic polymers that when blended together would be miscible, in order to form a miscible blend the polymer blend should contain at least one hydrophobic and one hydrophilic polymer which applicant does state in the further limitations in claims 7,16,26,27,38,40,60,61,67 and 68. The inherency argument is not made on probability or possibility since the disclosure encompasses the same type of polymer blends as applicant and can comprise an active

agent just as in applicants claims, the fact that the applicant claims they are miscible does not change the fact that the polymer blends are the same. There is a reasonable likelihood that someone skilled in the art who was looking for a coating for a medical device that comprises a polymer blend with an active agent incorporated within would find the Hossainy patent because that is exactly the field of endeavor the patent deals with, the fact that the applicant claims the polymer blends are miscible does not change the fact that the polymer blends are the same. Therefore since the polymers claimed in Hossainy are the same hydrophobic and hydrophilic polymers and can indeed be used in a blend, they are miscible. Regarding the statement that the blend controls the release of the active agent in an adjustable manner, this limitation was not expressed in the claims, at least how worded above and therefore was not searched by the examiner.

Claims 1-74 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483), for the reasons set forth in the office action mailed 03/09/2006.

Applicant asserts that there is no release data and no specific disclosure of the correlation of miscible polymer blends with the delivery of an active agent, in fact the time release of the drug could be controlled through the interactions between drug and stabilizing polymers. Applicant further states that that a stabilizing polymer is preferred to be crosslinkable, the above concepts are not relevant to polymer miscibility.

The relevance of these assertions is unclear. Clearly, since the polymers in Whitbourne can comprise the blends stated in applicants claims the polymer blend will have the same correlation for the release of the active agents since they are the same

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and would have the same properties. Regarding the assertion by applicant that the stabilizing polymer is preferably crosslinkable, just because it is a preferred embodiment it does not preclude the use of non-crosslinked stabilizing polymers.

Applicant asserts that where the term blend is used a “miscible” blend is not the only interpretation.

The relevance of this assertion is unclear. Clearly from the above argument Whitbourne can comprise the blends stated in applicants claims whether or not other combinations of polymers would not be miscible is of no concern when applying this art to applicants claimed invention.

Applicant asserts that in Exhibit B defines a “miscible polymer blend” as “a polymer blend homogenous down to the molecular level”.

The examiner interpreted miscible polymer blend to comprise at least two polymers, since there was no amendment to further limit this definition examiner relied on the claim interpretation that the two polymers are hydrophobic and hydrophilic when applying art, therefore the limitation of a miscible polymer blend is met. Even if the examiner used the definition above the Whitbourne patent would still meet the limitation that the polymer blend is homogenous down to the molecular level because the polymers and blends of those polymers are the same as those claimed by applicant.

Applicant asserts that Whitbourne is not enabled because the disclosure lacks enablement for an active agent delivery system that includes an active agent and a miscible polymer blend.

The relevance of this assertion is unclear. Clearly the specification discloses that a polymer blend can be used to coat a medical device while also delivering an active agent, many of the polymers in Whitbourne when blended together would be miscible, see above.

Applicant asserts that the examiners use of inherency because there is not specific disclosure that includes a combination of polymers that inherently form a miscible blend and can control the release of an active agent in an adjustable manner.

The relevance of this assertion is unclear. The examiner already stated above that since Whitbourne teaches many of the same polymer blends as applicant they would be miscible, in order to form a miscible blend the polymer blend should contain at least one hydrophobic and one hydrophilic polymer which applicant does state in the further limitations in claims 7,16,26,27,38,40,60,61,67 and 68. The inherency argument is not made on probability or possibility since the disclosure encompasses the same type of polymer blends as applicant and can comprise an active agent just as in applicants claims, the fact that the applicant claims they are miscible does not change the fact that the polymer blends are the same. There is a reasonable likelihood that someone skilled in the art who was looking for a coating for a medical device that comprises a polymer blend with an active agent incorporated within would find the Whitbourne patent because that is exactly the field of endeavor the patent deals with, the fact that the applicant claims the polymer blends are miscible does not change the fact that the polymer blends are the same. Therefore since the polymers claimed in Whitbourne are the same polymers and can indeed be used in a blend, they are



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miscible. Regarding the statement that the blend controls the release of the active agent in an adjustable manner, this limitation was not expressed in the claims, at least how worded above and therefore was not searched by the examiner.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252).

Claims 1-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483).

Applicant asserts that neither Hossainy nor Whitbourne provide guidance for one skilled in the art to select, as a polymer blend for an active agent delivery system, a miscible polymer as recited. Applicant also asserts that the selection of the particular relationships between the polymers and the active agent such that controlled delivery occurs is not a matter of routine experimentation and optimization of the composition.

Hossainy and Whitbourne are disclosed from the above. Obviously since both patents disclose the same polymer blends that can deliver an active agent just as applicants claimed invention the guidance is already disclosed within each patent. It is obvious that since the polymer blends can comprise the same polymers as applicants

claimed invention they would have the same properties including a controlled delivery of an active agent.

### ***Conclusion***

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

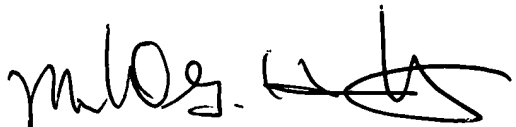
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 271-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER